

**REMARKS**

Claims 9-18 and 26-31 are pending.

Claims 9-18 and 26-31 were examined. Claims 9-15 and 26-31 were rejected. Claims 16-18 are allowed.

Claim 9 is amended. No new matter is added.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

**Allowable subject matter**

Applicants note with gratitude the Examiner's indication that claims 16-18 are allowed.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 9-15 and 26-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. The Applicants respectfully traverse this rejection.

Claim 9, a method claim, is rejected for failing to recite what the method is used for.

As Applicants understand it, then, the Office is rejecting claim 9 on the grounds it fails to recite its intended use.

As indicated in the MPEP<sup>1</sup>, a term that sets forth the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, is not considered a limitation and is of no significance to claim construction. Accordingly, the Applicants respectfully submit that this rejection is without basis, and may be withdrawn without further discussion.

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<sup>1</sup> See, for example, MPEP § 2111.02: "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation")"

However, solely to expedite prosecution and without any intention to acquiesce to the correctness of this rejection, the preamble of claim 9 has been amended to recite the phrase “method of screening for a bioactive agent”.

This amendment should create no new issue for the Examiner since the phrase “method of screening for a bioactive agent” is present in the previous version of claim 9.

The Applicants respectfully submit that this rejection has been adequately addressed, and, accordingly, this rejection may be withdrawn.

Claim 11 is rejected because it is unclear whether the labeling agent for detection of apoptotic cells labels the cells or if it labels the bioactive agent.

The Applicants respectfully submit that the subject matter encompassed by claim 11 would be clear to one of skill in the art because labeling agents for detecting apoptotic cells, e.g., ethidium bromide, acridine orange, propidium iodide, etc., are very well known in the art and are exemplified in the instant application (see, e.g., page 59, line 16). Typically, but not always, the agents bind DNA to detect nuclear disintegration – a well known feature of apoptotic cells. Accordingly, the labeling agents typically, but not always, label a component of the cells.

In any event, the Applicants respectfully submit that the Office is requiring that the Applicants recite a mechanism of action of the labeling agents recited in claim 11 for that claim to be understandable. However, as is well established in the law<sup>2</sup>, an understanding of the precise scientific mechanism by which a process works is not essential for patentability. According to the law, the precise mechanism by which the claim-recited labeling agents stain apoptotic cells should not be essential for the patentability of claim 11.

In view of the foregoing discussion, this rejection may be withdrawn.

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<sup>2</sup> *Philip Morris, Inc. v. Brown & Williamson Tobacco Corp.*, 641 F. Supp. 1438, 1483 n.13, 231 USPQ 321, 355 n.13 (M.D. Ga. 1986), supplemental opinion, 645 F. Supp. 174 (1986) (“understanding of the precise scientific mechanism by which the process works is not essential to patentability because scientific principles and natural phenomena are not patentable”)

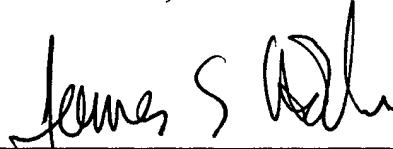
SUMMARY

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-002CON.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

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By:   
James S. Keddie, Ph.D.  
Registration No. 48,920

BOZICEVIC, FIELD & FRANCIS LLP  
200 Middlefield Road, Suite 200  
Menlo Park, CA 94025  
Telephone: (650) 327-3400  
Facsimile: (650) 327-3231